Author and Subject Indexes—Volume 10, 1975

Author Index

ANDERSON GH jt auth: Angiotensin II blockade in the hypertensive patient. 8:83

ATIENZA MF jt auth: Evaluation of abortion: techniques and protocols. 8:97

BAYLIN SB: Ectopic production of hormones and other proteins by tumors. 10:117

BEHRMAN SJ: Hazards of pregnancy. (editorial) 10:11

BERLIN NI: Research strategy in cancer: screening, diagnosis, prognosis. 1:83

BLUESTONE R: HL-A W27 and the 'rheumatoid variants.' 4:131

BOTTNOTT JK jt auth: Hepatitis induced by isoniazid and methyldopa. 4:119

BROWN GM: Psychiatric and neurologic aspects of endocrine disease. 8:71

BROWN JJ, FRASER R, LEVER AF, ROBERTSON JIS: Renovascular and other renal hypertension. 2:107

BRUNNER HR, GAVRAS H: Vascular damage in hypertension. 3:97

BUKANTZ SC: Deaths following insect stings. (editorial) 3:10

Malpractice: disaster . . . and opportunity? (editorial) 7:11

BURKMAN RT jt auth: Evaluation of abortion: techniques and protocols. 8:97

BURNETT LS, KING TM, BURKMAN RT, ATIENZA MF: Evaluation of abortion: techniques and protocols. 8:97

CIRIACY EW: Needed: family practice teachers. (editorial) 12:12

COMMONER B: (*see* Essays)

COPELAND EM III jt auth: Long-term parenteral nutrition: its current status. 5:47

DALAKOS TG jt auth: Angiotensin II blockade in the hypertensive patient. 8:83

DANCIS J: Prenatal diagnosis: a promise fulfilled. (editorial) 6:11

DAVIDSON JM: Hormones and sexual behavior in the male. 9:126

DAVIS BM jt auth: Hormones in the treatment of psychiatric disorders. 11:103

DAVIS KL jt auth: Hormones in the treatment of psychiatric disorders. 11:103

DOYLE AE: Sympathetic nervous activity in hypertension. 11:87

DUDRICK SJ, COPELAND EM III, MACFADYEN BV JR: Long-term parenteral nutrition: its current status. 5:47

EICKHOFF TC: (book review) 4:141

EISEMAN B: Military medicine in peacetime: the civilian physician's role. 6:115

FENN HH: Diagnosis by referendum. (editoral) 2:11

FILLMORE M: New NIH director's inheritance. (editorial) 8:11

FISHER DW: *JAMA* and pharmaceutical advertising. (editorial) 1:12

Whose 'Right to Life'? (editorial) 4:11

FORTUIN NJ: Echocardiography: what it can do now. 11:73

FOSTER JH, OATES JA: Recognition and management of renovascular hypertension. 10:61

FRASER R jt auth: Renovascular and other renal hypertension. 2:107

FREIBERG JM jt auth: Angiotension II blockade in the hypertensive patient. 8:83

FREMONT-SMITH P jt auth: Role of noninvasive techniques in diagnosing leg thrombosis. 12:57

FROHMAN LA: Neurotransmitters as regulators of endocrine function. 4:54

GAVRAS H jt auth: Vascular damage in hypertension. 3:97

GREEN M: Viral cell transformation in human oncogenesis. 9:91

HALLER JS: Enigmatic encephalopathy of Reye's syndrome. 2:91

HEIMLICH HJ: Esophagoplasty using reversed gastric tube. 7:80

HERBST AL, SCULLY RE, ROBBOY SJ: Effects of maternal DES ingestion on the female genital tract. 10:51

HERRINGTON JL JR: Management of postsurgical alkaline reflux gastritis. 11:53

HIRSH J: Venous thromboembolism: diagnosis, treatment, prevention. 8:53

HOFFMAN LS: New York's house staff strike: the maladies linger on. 6:143

HOLLISTER LE, DAVIS KL, DAVIS BM: Hormones in the treatment of psychiatric disorders. 11:103

HUME M, FREMONT-SMITH P: Role of noninvasive techniques in diagnosing leg thrombosis. 12:57

INGBAR SH: When to hospitalize the patient with thyrotoxicosis. 1:45

See also erratum 3:23

JAMPLIS RW: Practicing physician and patient education. 10:93

JAVITT NB: Chenodeoxycholic acid: the next phase. (editorial) 1:11

KING TM jt auth: Evaluation of abortion: techniques and protocols. 8:97

KLEIN JO: Shifts in microbial sensitivity: implications for pediatrics. 5:81

KRIEGER DT: Neuroendocrinology Series. 4:51

KRIEGER HP: Sellar and juxtasellar disease: a neurologic viewpoint. 6:95

KRISS JP: Graves' ophthalmopathy: etiology and treatment. 3:125

KRUGMAN S: Hepatitis: current status of etiology and prevention. 11:39

KUNIN CM: Who should treat infectious disease? (editorial) 9:11

LARAGH JH: Contraceptive hypertension: from 1967 on. (editorial) 5:13

LEDGER W: Ob/Gyn infections: changing patterns and management. 9:115

LEVER AF jt auth: Renovascular and other renal hypertension. 2:107

LIBERTINO J, ZINMAN L: Aorta-renal artery bypass for renovascular hypertension. 4:80

LICHTENSTEIN LM: Anaphylactic reactions to insect stings: a new approach. 3:67

LIEBMAN M: HOSPITAL PRACTICE's new look. (editorial) 3:13

LOGGIE JMH: Hypertension in children and adolescents. 6:81

MCEWEN BS: Brain as a target organ of endocrine hormones. 5:95

MACFADYEN BV JR jt auth: Long-term parenteral nutrition: its current status. 5:47

MCGIFF JC: Prostaglandins as regulators of blood pressure. 4:101

MADDREY WC, BOTTNOTT JK: Hepatitis induced by isoniazid and methyldopa. 4:119

MEDAWAR PB: (*see* Essays)

MICHAEL RP: Hormones and sexual behavior in the female. 12:69

MOROWITZ HJ: (*see* Essays)

MUIRHEAD EE: Antihypertensive function of the renal medulla. 1:99

MUSHER DM, SCHELL RF: Immunology of syphilis. 12:45

NADLER HL: Prenatal diagnosis of inborn defects: a status report. 6:41

NEW PFJ: Computed tomography: a major diagnostic advance. 2:55

NORMAN PS: Clinical significance of IgE. 8:41

OATES JA jt auth: Recognition and management of renovascular hypertension. 10:61

O'MALLEY BW: Hormones, genes, and cancer. 7:65

PAKTER J: (book review) 7:56

PAUMGARTNER G: Pharmacokinetic aspects of chenodeoxycholic acid therapy. 1:117

POPPER H, SCHAFFNER F: Management of viral hepatitis: old principles and new speculations. (editorial) 11:13

RANSOHOFF J: Diagnosis and treatment of minor subarachnoid hemorrhage. 5:109

ROBBOY SJ jt auth: Effects of maternal DES ingestion on the female genital tract. 10:51

ROBERTSON JIS jt auth: Renovascular and other renal hypertension. 2:107

ROSEMAN S: Sugars of the cell membrane. 1:61

RYTEL MW: Counterimmunoelectrophoresis in diagnosis of infectious disease. 10:75

SACHAR EJ: Hormonal changes in stress and mental illness. 7:49

SCHAFFNER F jt auth: Management of viral hepatitis: old principles and new speculations. (editorial) 11:13

SCHELL RF jt auth: Immunology of syphilis. 12:45

SCULLY RE jt auth: Effects of maternal DES ingestion on the female genital tract. 10:51

SEAMAN WB: (*see* X-Ray Casebook)

SEDGWICK CE, WOOL MS: Bilateral subtotal thyroidectomy for multinodular goiter. 2:70

SHINYA H, WOLFF WI: Colonoscopic polypectomy: technique and safety. 9:71

SMYTHE H: Nonsteroidal therapy in inflammatory joint disease. 9:51

STREETEN DHP, ANDERSON GH, FREIBERG JM, DALAKOS TG: Angiotensin II blockade in the hypertensive patient. 8:83

TAEUSCH HW JR: New directions in the management of RDS. 3:53

TARAZI RC: Heart in hypertension: its load and its role. 12:31

TOBIAN LJ JR: Clinical approach to essential hypertension. 7:33

TYLER DB: (book review) 2:154

UHL HSM: (book review) 11:34

UHR JW: Membranes of lymphocytes. 3:113

WALSER M: Treatment of renal failure with keto acids. 6:59

WEINBERGER MH: Oral contraceptives and hypertension. 5:65

WEISSMANN G: Marat on sabbatical. 7:103

WOLFF WI jt auth: Colonoscopic polypectomy: technique and safety. 9:71

WOOL MS jt auth: Bilateral subtotal thyroidectomy for multinodular goiter. 2:70

ZINMAN L jt auth: Aorta-renal artery bypass for renovascular hypertension. 4:80

ZOLL PM: Countershock and pacemaking in cardiac arrhythmias. 2:125

Subject Index

ABORTION

Evaluation of abortion: techniques and protocols. Burnett, King, Burkman, Atienza, 8:97

Whose 'Right to Life'? (editorial) Fisher, 4:11

ACHALASIA OF ESOPHAGUS *see* CARDIOSPASM

ADENOCARCINOMA

Effects of maternal DES ingestion on the female genital tract. Herbst, Scully, Robboy, 10:51

ADENOIDECTOMY

Teaching hospitals found heavy antibiotic users for T & As. 3:89

ADENOMA, CHROMOPHOBE

Sellar and juxtasellar disease: a neurologic viewpoint. Krieger, 6:95

ADJUVANT ARTHRITIS *see* ARTHRITIS, RHEUMATOID

ADRENOMIMETICS *see* SYMPATHOMIMETICS

AEROSOLS

Aerosols: how dangerous for asthma patients? 2:40

ALLERGY *see* HYPERSENSITIVITY

AMERICAN MEDICAL ASSOCIATION

AMA: Board cutback moves swamped by delegate revolt. 1:24

Financially upset AMA trims publications, ups dues. 8:115

Industrial union precedents spread to health care industry. 8:111

AMNIOCENTESIS

Prenatal diagnosis: a promise fulfilled. (editorial) Dancis 6:11

Prenatal diagnosis of inborn defects: a status report. Nadler, 6:41

AMPICILLIN
Shifts in microbial sensitivity: implications for pediatrics. Klein, 5:81
ANGIOTENSIN II
Angiotensin II blockade in the hypertensive patient. Streeten, Anderson, Frieberg, Dalakos, 8:83
Vascular damage in hypertension. Brunner, Gavras, 3:97
ANTIGENS
Membranes of lymphocytes. Uhr, 3:113
ANTIHYPERTENSIVE AGENTS
Clinical approach to essential hypertension. Tobian, 7:33
Heart in hypertension: its load and its role. Tarazi, 12:31
How well do physicians use antihypertensive drugs? 10:29
ARRHYTHMIA
Countershock and pacemaking in cardiac arrhythmias. Zoll, 2:125
ARTHRITIS, RHEUMATOID
Nonsteroidal therapy in inflammatory joint disease. Smythe, 9:51
ASBESTOSIS
Case of the dusty lung. Seaman, 4:94
ASPIRIN
Nonsteroidal therapy in inflammatory joint disease. Smythe, 9:51
ASTHMA
Aerosols: how dangerous for asthma patients? 2:40
Drug therapy in asthma: more rational, still complex. 2:27
AUTONOMIC DRUGS
Neurotransmitters as regulators of endocrine function. Frohman, 4:54
AZATHIOPRINE
Nonsteroidal therapy in inflammatory joint disease. Smythe, 9:51

BLOOD BANKS
Computers, supermarket style, may soon help run blood banking. 8:114
BLOOD PRESSURE, HIGH *see* HYPERTENSION
BOOKS IN CONTEXT (book reviews)
Clinical Perinatology. Aladjem, Brown, ed, 7:56
Infection in Hospital: a Code of Practice. 2d ed. Gibson, ed, 4:141
PSRO: Organization for Regional Peer Review. Decker, Bonner, ed, 11:34
Psychiatric Diagnosis. Woodruff, Goodwin, Guze, 2:154
BRAIN
Brain as a target organ of endocrine hormones. McEwen, 5:95
BRAIN DISEASES
Enigmatic encephalopathy of Reye's syndrome. Haller, 2:91
BRAIN NEOPLASMS
Computed tomography: a major diagnostic advance. New, 2:55
BREAST NEOPLASMS
Hormones, genes, and cancer. O'Malley, 7:65
Ultrasound highly recommended in diagnosis of breast cancer. 11:26B
BURNS
Long-term parenteral nutrition; its current status. Dudrick, Copeland, MacFadyen, 5:47

CALCITONIN
Ectopic production of hormones and other proteins by tumors. Baylin, 10:117
CANCER *see* NEOPLASMS
CARCINOGENS, ENVIRONMENTAL
Mutagenesis: a probe for carcinogenicity. Commoner, 3:43
CARDIAC ARREST *see* HEART ARREST
CARDIAC OUTPUT
Heart in hypertension; its load and its role. Tarazi, 12:31
CARDIOSPASM
Esophagoplasty using reversed gastric tube. Heimlich, 7:80
CARDIOVERSION *see* ELECTRIC COUNTERSHOCK
CELL MEMBRANE SERIES
Membranes of lymphocytes. Uhr, 3:113
Sugars of the cell membrane. Roseman, 1:61
CELL TRANSFORMATION, NEOPLASTIC
Ectopic production of hormones and other proteins by tumors. Baylin, 10:117
Viral cell transformation in human oncogenesis. Green, 9:91
CEREBRAL ISCHEMIA, TRANSIENT
Diagnosis and treatment of minor subarachnoid hemorrhage. Ransohoff, 5:109
CEREBROVASCULAR DISORDERS
Computed tomography: a major diagnostic advance. New, 2:55
CERVIX, NEOPLASMS
Effects of maternal DES ingestion on the female genital tract. Herbst, Scully, Robboy, 10:51
CHENODEOXYCHOLIC ACID
Chenodeoxycholic acid: the next phase. (editorial) Javitt, 1:11
Pharmacokinetic aspects of chenodeoxycholic acid therapy. Paumgartner, 1:117
CHLOROQUINE
Nonsteroidal therapy in inflammatory joint disease. Smythe, 9:51
CHOLECYSTECTOMY
Chenodeoxycholic acid: the next phase. (editorial) Javitt, 1:11
CLINIC AND CLASSROOM
Alone in Brooklyn: how does the FP training tree grow? 7:126
See also letter 9:16
Emergency physicians gear up for specialty approval. 10:131
Financially beset AMA trims publications, ups dues. 8:115
FP as teacher of FP. 2:155
Malpractice debate: doctors, lawyers – friends or foes? 5:149
Med schools want no strings attached to federal money. 1:142
New York's house staff strike: the maladies linger on. 6:143
Physician's practice profile guides continuing education. 3:29
Under way: specialty boards' voluntary recertification plans. 4:42
CLINICAL DATA CORRELATIONS
Teaching hospitals found heavy antibiotic users for T & As. 3:89
Which children are hospitalized where. 10:95 (1974)
See also letter 2:15 (1975)
COLONIC DISEASES
Colonoscopic polypectomy: technique and safety. Shinya, Wolff, 9:71
COMMITTEE OF INTERNS AND RESIDENTS (New York City)
New York's house staff strike: the maladies linger on. 6:143
COMMUNICABLE DISEASES
Counterimmunoelectrophoresis in diagnosis of infectious disease. Rytel, 10:75
Who should treat infectious disease? (editorial) Kunin, 9:11
COMPUTERS
Computed tomography: a major diagnostic advance. New, 2:55
On computers, free will, and creativity. Morowitz, 10:87
CONTRACEPTIVES, ORAL
Contraceptive hypertension: from 1967 on. (editorial) Laragh, 5:13
Oral contraceptives and hypertension. Weinberger, 5:65
CORDAY C
Marat on sabbatical. Weissmann, 7:103
CORTISOL *see* HYDROCORTISONE
CRANIOPHARYNGIOMA
Sellar and juxtasellar disease: a neurologic viewpoint. Krieger, 6:95
CROMOLYN SODIUM *see* DISODIUM CROMOGLYCATE
CYPROTERONE
Hormones and sexual behavior in the male. Davidson, 9:126

DBI *see* PHENFORMIN
DEATH RATE *see* MORTALITY
DEFIBRILLATION, ELECTRIC *see* ELECTRIC COUNTERSHOCK
DEMENTIA PRAECOX *see* SCHIZOPHRENIA
DEPRESSION
Hormonal changes in stress and mental illness. Sachar, 7:49
DIABETES MELLITUS
Diabetes: shifting concepts in diagnosis, therapy, etiology. 8:23
Islet cell transplantation for diabetes: how good? when? 4:24
DIAGNOSIS, LABORATORY
Counterimmunoelectrophoresis in diagnosis of infectious disease. Rytel, 10:75
Who should treat infectious disease? (editorial) Kunin, 9:11
DIALYSIS, EXTRACORPOREAL *see* HEMODIALYSIS
DIETARY PROTEINS
Treatment of renal failure with keto acids. Walser, 6:59
DIETHYLSTILBESTROL
Effects of maternal DES ingestion on the female genital tract. Herbst, Scully, Robboy, 10:51
Hazards of pregnancy. (editorial) Behrman, 10:11
DILATATION AND CURETTAGE
Evaluation of abortion: techniques and protocols. Burnett, King, Burkman, Atienza, 8:97
DISODIUM CROMOGLYCATE
Drug therapy in asthma: more rational, still complex. 2:27
DIURETICS, THIAZIDE
Clinical approach to essential hypertension. Tobian, 7:33
DOPAMINE BETA HYDROXYLASE
Sympathetic nervous activity in hypertension. Doyle, 11:87
DRUG RESISTANCE, MICROBIAL
Shifts in microbial sensitivity: implications for pediatrics. Klein, 5:81

ECHOCARDIOGRAPHY
Echocardiography: what it can do now. Fortuin, 11:73
EDITORIALS
Chenodeoxycholic acid: the next phase. Javitt, 1:11
Contraceptive hypertension: from 1967 on. Laragh, 5:13
Deaths following insect stings. Bukantz, 3:10
Diagnosis by referendum. Fenn, 2:11
See also letters 4:17; 9:16; 12:17
Hazards of pregnancy. Behrman, 10:11
HOSPITAL PRACTICE's new look. Liebman, 3:13
JAMA and pharmaceutical advertising. Fisher, 1:12
Malpractice: disaster . . . and opportunity? Bukantz, 7:11
Management of viral hepatitis: old principles and new speculations. Popper, Schaffner, 11:13
Needed: family practice teachers. Ciriacy, 12:12
New NIH director's inheritance. Fillmore, 8:11
Prenatal diagnosis: a promise fulfilled. Dancis, 6:11
Who should treat infectious disease? Kunin, 9:11
Whose 'Right to Life'? Fisher, 4:11
ELECTRIC COUNTERSHOCK
Countershock and pacemaking in cardiac arrhythmias. Zoll, 2:125
ENDOCARDITIS
Prosthetic endocarditis may dictate reoperation. 2:45

ENDOCRINE DISEASES
Neurotransmitters as regulators of endocrine function. Frohman, 4:54
Psychiatric and neurologic aspects of endocrine disease. Brown, 8:71
ENDOSCOPY
Colonoscopic polypectomy: technique and safety. Shinya, Wolff, 9:71
ESOPHAGEAL DISEASES
Case of the intramural pseudodiverticula. Seaman. 6:72
ESOPHAGOPLASTY
Esophagoplasty using reversed gastric tube. Heimlich, 7:80
ESSAYS
After 5 years: what on 'earth'? Commoner, 5:167
Cancer as an environmental disease. Commoner, 2:82
Cell types: the Great Divide. Morowitz, 1:135
Compostable newspaper in the organic garden. Commoner, 7:23
Fair is foul, and foul is fair. Morowitz, 5:35
From Percival Pott to Henry Kissinger. Commoner, 10:138
Helmholtz, Mayer, and the M.D.-Ph.D. program. Morowitz, 3:169
Hiding in the Hammond report. Morowitz, 8:35
Life wasn't built in a day. Commoner, 1:74
Lox et veritas. Morowitz, 2:163
Mutagenesis: a probe for carcinogenicity. Commoner, 3:43
New math for the CNS? Morowitz, 9:81
On computers, free will, and creativity. Morowitz, 10:87
On first looking into Bergey's manual. Morowitz, 4:156
On riding a biocycle. Morowitz, 11:114
'Plastic to plastic.' Commoner, 11:67
Rose (natural) is a rose (organic) is a rose? Commoner, 4:147
Science, society, and serendipity. Commoner, 9:59
Smallest free living cell. Morowitz, 7:95
Social implications of a biologic principle. Morowitz, 6:155
Sole on fire. Morowitz, 12:24
Some follies of prediction. Medawar 4:73
Urban biology: its ecosystem needs a lab. Commoner, 6:110
Whose uranium? Commoner, 8:119
ESTRADIOL
Brain as a target organ of endocrine hormones. McEwen, 5:95

FAMILY PRACTICE
Alone in Brooklyn: how does the FP training tree grow? 7:126
FP as teacher of FP. 2:155
Needed: family practice teachers. (editorial) Ciriacy, 12:12
FATTY LIVER
Enigmatic encephalopathy of Reye's syndrome. Haller, 2:91
FATTY TUMOR *see* LIPOMA
FEATURE
Intragastric camera: through 16 simultaneous exposures it maps 95% of the stomach's interior. 3:80
FERRITIN
New serum radioassay spots subtle iron deficiencies. 4:36
FETAL DISEASES
Prenatal diagnosis of inborn defects: a status report. Nadler, 6:41
FREDRICKSON DS
New NIH director's inheritance. (editorial) Fillmore, 8:11

GASTROENTEROSTOMY
Management of postsurgical alkaline reflux gastritis. Herrington, 11:53
GASTROINTESTINAL DISEASES
Long-term parenteral nutrition: its current status. Dudrick, Copeland, MacFadyen, 5:47
GENERAL PRACTICE *see* FAMILY PRACTICE
GLUCOCORTICOIDS
New directions in the management of RDS. Taeusch, 5:23
GLYCOPROTEINS
Sugars of the cell membrane. Roseman, 1:61
GOITER, EXOPHTHALMIC
Graves' ophthalmopathy: etiology and treatment. Kriss, 3:125
When to hospitalize the patient with thyrotoxicosis. Ingbar, 1:45
See also erratum 3:23
GOITER, NODULAR
Bilateral subtotal thyroidectomy for multinodular goiter. Sedgwick, Wool, 2:70
GOLD THIOMALATE
Nonsteroidal therapy in inflammatory joint disease. Smythe, 9:51
GONOCOCCUS *see* NEISSERIA GONORRHOEAE
GOVERNMENT IMPACT ON HOSPITAL PRACTICE
Computers, supermarket style, may soon help run blood banking. 8:114
Congress, HEW at odds over HMOs' slow growth. 10:145
Federal licensing, inspection of physicians' labs possible. 11:31
Federal regulations force changes in nursing home care. 2:134
Health benefits for jobless: road to national insurance? 6:132
Health budget: numbers game or revenue sharing in reverse? 4:151
Industrial union precedents spread to health care industry. 8:111
Moves afoot to shore up sagging malpractice coverage. 5:24
Too many hospital beds? Naderite gadfly stings again. 7:113
Unnecessary surgery: focus for surgeons and congressmen. 9:138
GRAVES' DISEASE *see* GOITER, EXOPHTHALMIC
GROWTH HORMONE, PITUITARY *see* SOMATOTROPIN
GYNECOLOGY
Ob/Gyn infections: changing patterns and management. Ledger, 9:115

HAEMOPHILUS INFLUENZAE
Shifts in microbial sensitivity: implications for pediatrics. Klein, 5:81
HEART ARREST
Countershock and pacemaking in cardiac arrhythmias. Zoll, 2:125
HEART VALVE PROSTHESIS
Prosthetic endocarditis may dictate reoperation. 2:45
HEMODIALYSIS
Renovascular and other renal hypertension. Brown, Fraser, Lever, Robertson, 2:107
HEMORRHAGE, SUBARACHNOID *see* SUBARACHNOID HEMORRHAGE
HEPARIN
Venous thromboembolism: diagnosis, treatment, prevention. Hirsh, 8:53
HEPATITIS
Chronic aggressive hepatitis responds to transfer factor. 10:25
Hepatitis: current status of etiology and prevention. Krugman, 11:39
Hepatitis induced by isoniazid and methyldopa. Maddrey, Boitnott, 4:119
Management of viral hepatitis: old principles and new speculations. (editorial) Popper, Schaffner, 11:13
Rising threats to newborn: group B strep, hepatitis B. 6:27
HEREDITARY DISEASES
Prenatal diagnosis of inborn defects: a status report. Nadler, 6:41
HISTAMINASE
Ectopic production of hormones and other proteins by tumors. Baylin, 10:117

HISTOCOMPATIBILITY ANTIGENS
HL-A W27 and the 'rheumatoid variants.' Bluestone, 4:131
HOMOSEXUALITY
Diagnosis by referendum. (editorial) Fenn, 2:11
HORMONES
Hormones and sexual behavior in the female. Michael, 12:69
Hormones and sexual behavior in the male. Davidson, 9:126
Hormones, genes, and cancer. O'Malley 7:65
Hormones in the treatment of psychiatric disorders. Hollister, Davis, Davis, 11:103
Psychiatric and neurologic aspects of endocrine disease. Brown, 8:71
HORMONES, ECTOPIC
Ectopic production of hormones and other proteins by tumors. Baylin, 10:117
HYDROCORTISONE
Hormonal changes in stress and mental illness. Sachar, 7:49
HYPERSENSITIVITY
Clinical significance of IgE. Norman, 8:41
HYPERTENSION SERIES
Angiotensin II blockade in the hypertensive patient. Streeten, Anderson, Freiberg, Dalakos, 8:83
Antihypertensive function of the renal medulla. Muirhead, 1:99
Clinical approach to essential hypertension. Tobian, 7:33
Heart in hypertension: its load and its role. Tarazi, 12:31
Hypertension in children and adolescents. Loggie, 6:81
Oral contraceptives and hypertension. Weinberger, 5:65
Prostaglandins as regulators of blood pressure. McGiff, 4:101
Recognition and management of renovascular hypertension. Foster, Oates, 10:61
Renovascular and other renal hypertension. Brown, Fraser, Lever, Robertson, 2:107
Sympathetic nervous activity in hypertension. Doyle, 11:87
Vascular damage in hypertension. Brunner, Gavras, 3:97
HYPERTHYROIDISM
When to hospitalize the patient with thyrotoxicosis. Ingbar, 1:45
See also erratum 3:23
HYPOTHALAMUS
Neurotransmitters as regulators of endocrine function. Frohman, 4:54

IGE
Clinical significance of IgE. Norman, 8:41
IMMUNOELECTROPHORESIS
Counterimmunoelectrophoresis in diagnosis of infectious disease. Rytel, 10:75
IMURAN *see* AZATHIOPRINE
INDERAL *see* PROPRANOLOL
INDIA
In India: a flickering light in darkness of abject misery. 5:120
India II: a tale of untreated patients and unemployed MDs. 9:22
INFANT, NEWBORN, DISEASES
New directions in the management of RDS. Taeusch, 3:53
Rising threat to newborn: group B strep, hepatitis B. 6:27
Shifts in microbial sensitivity: implications for pediatrics. Klein, 5:81
INFLUENZA VACCINE
Can 'Alice' outflank the influenza A virus? 1:129
INSECT BITES AND STINGS
Anaphylactic reactions to insect stings: a new approach. Lichtenstein, 3:67
Deaths following insect stings. (editorial) Bukantz, 3:10
INTERNATIONAL PIGMENT CELL CONFERENCE, 9th, Houston

Malignant melanoma plus & minus: better therapy, higher incidence. 6:33

INTRAVENOUS FEEDING *see* PARENTERAL FEEDING

ISONIAZID
Hepatitis induced by isoniazid and methyldopa. Maddrey, Boitnott, 4:119

JOINT DISEASES
Nonsteroidal therapy in inflammatory joint disease. Smythe, 9:51

KALLIKREIN
Prostaglandins as regulators of blood pressure. McGiff, 4:101

KETO ACIDS
Treatment of renal failure with keto acids. Walser, 6:59

KIDNEY DISEASES
When to suspect analgesic abuse in renal disease. 3:24

KIDNEY FAILURE, CHRONIC
For hypercalcemia of renal failure: parathyroid grafts. 7:25
Renovascular and other renal hypertension. Brown, Fraser, Lever, Robertson, 2:107
Treatment of renal failure with keto acids. Walser, 6:59

KIDNEY FUNCTION TESTS
Recognition and management of renovascular hypertension. Foster, Oates, 10:61

KININOGENASE *see* KALLIKREIN

LACTOGENIC HORMONE, PITUITARY, *see* PROLACTIN

LATS *see* LONG-ACTING THYROID STIMULATOR

LEISURE OF THE THEORIED CLASS
Marat on sabbatical. Weissmann, 7:103

LEUKEMIA
High urinary output, pH help with methotrexate. 10:26

LEUKOVIRUSES *see* ONCOGENIC VIRUSES

LIPOMA
Case of the fatty tumor. Seaman, 9:144

LONG-ACTING THYROID STIMULATOR
Graves' ophthalmopathy: etiology and treatment. Kriss, 3:125

LUNG NEOPLASMS
Case of the dusty lung. Seaman, 4:94

MALPRACTICE
Malpractice debate: doctors, lawyers – friends or foes? 5:149
Malpractice: disaster . . . and opportunity? (editorial) Bukantz, 7:11
Moves afoot to shore up sagging malpractice coverage. 5:24
Under way: specialty boards' voluntary recertification plans. 4:42

MARAT JP
Marat on sabbatical. Weissmann, 7:103

MASS SCREENING
Research strategy in cancer: screening, diagnosis, prognosis. Berlin, 1:83

MEDICINE AROUND THE WORLD
Desperate for health care, Philippines exports MDs. 10:36
How 'socialized medicine' works in Saskatchewan. 3:137
In India: a flickering light in darkness of abject misery. 5:120
India II: a tale of untreated patients and unemployed MDs. 9:22

MELANOMA
Malignant melanoma plus & minus: better therapy, higher incidence. 6:33

MENINGOCOCCAL INFECTIONS
Meningococcus vaccine – yes; gonococcus – no. 1:37
Shifts in microbial sensitivity: implications for pediatrics. Klein, 5:81

MENTAL DISORDERS
Hormones in the treatment of psychiatric disorders. Hollister, Davis, Davis, 11:103

METHOTREXATE
High urinary output, pH help with methotrexate. 10:26

METHYLDOPA
Hepatitis induced by isoniazid and methyldopa. Maddrey, Boitnott, 4:119

MILITARY MEDICINE
Military medicine in peacetime: the civilian physician's role. Eiseman, 6:115

MINERALOCORTICOIDS
Vascular damage in hypertension. Brunner, Gavras, 3:97

MITRAL VALVE DISEASES
Echocardiography: what it can do now. Fortuin, 11:73

NATIONAL CANCER INSTITUTE
Research strategy in cancer: screening, diagnosis, prognosis. Berlin, 1:83

NEISSERIA GONORRHOEAE
Meningococcus vaccine – yes; gonococcus – no. 1:37

NEOPLASMS
Computed tomography: a major diagnostic advance. New, 2:55
Ectopic production of hormones and other proteins by tumors. Baylin, 10:117
Long-term parenteral nutrition: its current status. Dudrick, Copeland, MacFadyen, 5:47
Research strategy in cancer: screening, diagnosis, prognosis. Berlin, 1:83

NEUROENDOCRINOLOGY SERIES
Brain as a target organ of endocrine hormones. McEwen, 5:95
Hormonal changes in stress and mental illness. Sachar, 7:49
Hormones and sexual behavior in the female. Michael, 12:69
Hormones and sexual behavior in the male. Davidson 9:126
Hormones in the treatment of psychiatric disorders. Hollister, Davis, Davis, 11:103
Neuroendocrinology Series. (introduction) Krieger, 4:51
Neurotransmitters as regulators of endocrine function. Frohman, 4:54
Psychiatric and neurologic aspects of endocrine disease. Brown, 8:71
Sellar and juxtasellar disease: a neurologic viewpoint. Krieger, 6:95

NEWS OF HOSPITAL INTEREST
Aerosols: how dangerous for asthma patients? 2:40
AMA: Board cutback moves swamped by delegate revolt. 1:24
Can 'Alice' outflank the influenza A virus? 1:129
Chronic aggressive hepatitis responds to transfer factor. 10:25
Diabetes: shifting concepts in diagnosis, therapy, etiology. 8:23
Drug therapy in asthma: more rational, still complex. 2:27
For hypercalcemia of renal failure: parathyroid grafts. 7:25
High urinary output, pH help with methotrexate. 10:26
House officers vote yes for national union. 12:18
How well do physicians use antihypertensive drugs? 10:29
Islet cell transplantation for diabetes: how good? when? 4:24
Malignant melanoma plus & minus: better therapy, higher incidence. 6:33
Meningococcus vaccine – yes; gonococcus – no. 1:37
New serum radioassay spots subtle iron deficiencies. 4:36
Prosthetic endocarditis may dictate reoperation. 2:45
Rat-bite fever a lab job risk. 2:53
See also letters 4:17; 6:24
Rising threats to newborn: group B strep, hepatitis B. 6:27
Ultrasound highly recommended in diagnosis of breast cancer. 11:26B
When to suspect analgesic abuse in renal disease. 3:24

Whenever an APC/narcotic is indicated.

Percodan® Tablets ©

Each yellow, scored tablet contains 4.50 mg. oxycodone HCl (Warning: May be habit forming), 0.38 mg. oxycodone terephthalate (Warning: May be habit forming), 224 mg. aspirin, 160 mg. phenacetin, and 32 mg. caffeine.

INDICATIONS: For the relief of moderate to moderately severe pain.

CONTRAINDICATIONS: Hypersensitivity to oxycodone, aspirin, phenacetin or caffeine.

WARNINGS: *Drug Dependence:* Oxycodone can produce drug dependence of the morphine type and, therefore, has the potential for being abused. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of Percodan, and it should be prescribed and administered with the same degree of caution appropriate to the use of other oral narcotic-containing medications. Like other narcotic-containing medications, Percodan is subject to the Federal Controlled Substances Act.

Usage in ambulatory patients: Oxycodone may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. The patient using Percodan should be cautioned accordingly.

Interaction with other central nervous system depressants: Patients receiving other narcotic analgesics, general anesthetics, phenothiazines, other tranquilizers, sedative-hypnotics or other CNS depressants (including alcohol) concomitantly with Percodan may exhibit an additive CNS depression. When such combined therapy is contemplated, the dose of one or both agents should be reduced.

Usage in pregnancy: Safe use in pregnancy has not been established relative to possible adverse effects on fetal development. Therefore, Percodan should not be used in pregnant women unless, in the judgment of the physician, the potential benefits outweigh the possible hazards.

Usage in children: Percodan should not be administered to children.

Salicylates should be used with caution in the presence of peptic ulcer or coagulation abnormalities.

PRECAUTIONS: *Head injury and increased intracranial pressure:* The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a pre-existing increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.

Acute abdominal conditions: The administration of Percodan or other narcotics may obscure the diagnosis or clinical course in patients with acute abdominal conditions.

Special risk patients: Percodan should be given with caution to certain patients such as the elderly or debilitated, and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, and prostatic hypertrophy or urethral stricture.

Phenacetin has been reported to damage the kidneys when taken in excessive amounts for a long time.

ADVERSE REACTIONS: The most frequently observed adverse reactions include light-headedness, dizziness, sedation, nausea and vomiting. Some of these adverse reactions may be alleviated if the patient lies down.

Other adverse reactions include euphoria, dysphoria, constipation and pruritus.

DOSAGE AND ADMINISTRATION: Dosage should be adjusted according to the severity of the pain and the response of the patient. It may occasionally be necessary to exceed the usual dosage recommended below in cases of more severe pain or in those patients who have become tolerant to the analgesic effect of narcotics. The usual adult dose is one tablet every six hours as needed for pain.

DRUG INTERACTIONS: The CNS depressant effects of Percodan may be additive with that of other CNS depressants. See WARNINGS.

Aspirin may enhance the effect of anticoagulants and inhibit the effect of uricosuric agents.

MANAGEMENT OF OVERDOSAGE: *Signs and Symptoms:* Serious overdose with Percodan is characterized by respiratory depression, extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdosage, apnea, circulatory collapse, cardiac arrest and death may occur. The ingestion of very large amounts of Percodan may, in addition, result in acute salicylate intoxication.

Treatment: Primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation. The narcotic antagonists naloxone, nalorphine or levallorphan are specific antidotes against respiratory depression which may result from overdosage or unusual sensitivity to narcotics, including oxycodone. Therefore, an appropriate dose of one of these antagonists should be administered, preferably by the intravenous route, simultaneously with efforts at respiratory resuscitation. Since the duration of actionf of oxycodone may exceed that of the antagonist, the patient should be kept under continued surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration.

An antagonist should not be administered in the absence of clinically significant respiratory or cardiovascular depression.

Oxygen, intravenous fluids, vasopressors and other supportive measures should be employed as indicated.

Gastric emptying may be useful in removing unabsorbed drug.

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DUPONT

NOREPINEPHRINE
Sympathetic nervous activity in hypertension. Doyle, 11:87
NUTRITION
Long-term parenteral nutrition: its current status. Dudrick, Copeland, MacFadyen, 5:47

OBSTETRICS
Ob/Gyn infections: changing patterns and management. Ledger, 9:115
OLIGOSACCHARIDES
Sugars of the cell membrane. Roseman, 1:61
ONCOGENIC VIRUSES
Viral cell transformation in human oncogenesis. Green, 9:91

PACEMAKER, ARTIFICIAL
Countershock and pacemaking in cardiac arrhythmias. Zoll, 2:125
PARATHYROID GLANDS
For hypercalcemia of renal failure: parathyroid grafts. 7:25
PARENTERAL FEEDING
Long-term parenteral nutrition: its current status. Dudrick, Copeland, MacFadyen, 5:47
PEER REVIEW PERSPECTIVES
Periodic review Rx: personal touch, flexibility, persistence. 2:145
PHENFORMIN
Diabetes: shifting concepts in diagnosis, therapy, etiology. 8:23
PHEROMONES
Hormones and sexual behavior in the female. Michael, 12:69
PHOTOGRAPHY
Intragastric camera: through 16 simultaneous exposures it maps 95% of the stomach's interior. 3:80
PHYSICIANS NATIONAL HOUSESTAFF ASSOCIATION
House officers vote yes for national union. 12:18
PITUITARY NEOPLASMS
Sellar and juxtasellar disease: a neurologic viewpoint. Krieger, 6:95
PLETHYSMOGRAPHY, IMPEDANCE
Role of noninvasive techniques in diagnosing leg thrombosis. Hume, Fremont-Smith, 12:57
POLYPS
Colonoscopic polypectomy: technique and safety. Shinya, Wolff, 9:71
PORPHYRIA
Marat on sabbatical. Weissmann, 7:103
PRENATAL DIAGNOSIS
Prenatal diagnosis a promise fulfilled. (editorial) Dancis, 6:11
Prenatal diagnosis of inborn defects: a status report. Nadler, 6:41
PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS
Federal regulations force changes in nursing home care. 2:134
PROLACTIN
Hormonal changes in stress and mental illness. Sachar, 7:49
Neurotransmitters as regulators of endocrine function. Frohman, 4:54
PROPRANOLOL
Angiotensin II blockade in the hypertensive patient. Streeten, Anderson, Frieberg, Dalakos, 8:83
PROSTAGLANDINS
Antihypertensive function of the renal medulla. Muirhead, 1:99
Evaluation of abortion: techniques and protocols. Burnett, King, Burkman, Atienza, 8:97
Prostaglandins as regulators of blood pressure. McGiff, 4:101
PULMONARY ALVEOLAR PROTEINOSIS
Case of the cloudy lungs. Seaman, 7:122
PULMONARY EMBOLISM
Venous thromboembolism: diagnosis, treatment, prevention. Hirsh, 8:53
PULMONARY NEOPLASMS *see* LUNG NEOPLASMS
PULMONARY SURFACTANT
New directions in the management of RDS. Taeusch, 3:53

RADIOIMMUNOASSAY
New serum radioassay spots subtle iron deficiencies. 4:36
RADIOISOTOPE RENOGRAPHY
Recognition and managment of renovascular hypertension. Foster, Oates, 10:61
RADIOTHERAPY, HIGH ENERGY
Graves' ophthalmopathy: etiology and treatment. Kriss, 3:125
RAT-BITE FEVER
Rat-bite fever a lab job risk. 2:53
REITER'S DISEASE
HL-A W27 and the 'rheumatoid variants.' Bluestone, 4:131
RENAL ARTERY OBSTRUCTION
Aorta-renal artery bypass for renovascular hypertension. Libertino, Zinman, 4:80
Recognition and management of renovascular hypertension. Foster, Oates, 10:61
RENAL FAILURE, CHRONIC *see* KIDNEY FAILURE, CHRONIC
RENIN *see* HYPERTENSION SERIES
RENOGRAPHY *see* RADIOISOTOPE RENOGRAPHY
RESIDENCY ASSISTANCE PROGRAM
Needed: family practice teachers. (editorial) Ciriacy, 12:12
RESPIRATORY DISTRESS SYNDROME
New directions in the management of RDS. Taeusch, 3:53
REVERSE TRANSCRIPTASE
Viral cell transformation in human oncogenesis. Green, 9:91
REYE'S SYNDROME *see* BRAIN DISEASES
RHEOGRAPHY *see* PLETHYSMOGRAPHY, IMPEDANCE
RHEUMATISM
HL-A W27 and the 'rheumatoid variants.' Bluestone, 4:131
RIFAMPIN
Shifts in microbial sensitivity: implications for pediatrics. Klein, 5:81
RNA-DEPENDENT DNA POLYMERASE *see* REVERSE TRANSCRIPTASE

SAPHENOUS VEIN
Aorta-renal artery bypass for renovascular hypertension. Libertino, Zinman, 4:80
SCHIZOPHRENIA
Hormonal changes in stress and mental illness. Sachar, 7:49
SELLA TURCICA
Sellar and juxtasellar disease: a neurologic viewpoint. Krieger, 6:95
SOCIETY OF TEACHERS OF FAMILY MEDICINE
Needed: family practice teachers. (editorial) Ciriacy, 12:12
SOMATOSTATIN *see* SOMATOTROPIN RELEASE INHIBITING HORMONE
SOMATOTROPIN
Neurotransmitters as regulators of endocrine function. Frohman, 4:54
SOMATOTROPIN RELEASE INHIBITING HORMONE
Diabetes: shifting concepts in diagnosis, therapy, etiology. 8:23
SPONDYLITIS, ANKYLOSING
HL-A W27 and the 'rheumatoid variants.' Bluestone, 4:131
STAPHYLOCOCCAL INFECTIONS
Shifts in microbial sensitivity: implications for pediatrics. Klein, 5:81
STREPTOCOCCAL INFECTIONS
Rising threats to newborn: group B strep, hepatitis B. 6:27
STRESS, PSYCHOLOGICAL
Hormonal changes in stress and mental illness. Sachar, 7:49
STROKE *see* CEREBROVASCULAR DISORDERS
SUBARACHNOID HEMORRHAGE
Diagnosis and treatment of minor subarachnoid hemorrhage. Ransohoff, 5:109
SUPRASELLAR CYST *see* CRANIOPHARYNGIOMA
SURGICAL-MEDICAL SERIES
Aorta-renal artery bypass for renovascular hypertension. Libertino, Zinman, 4:80
Bilateral subtotal thyroidectomy for multinodular goiter. Sedgwick, Wool, 2:70
Esophagoplasty using reversed gastric tube. Heimlich, 7:80
Management of postsurgical alkaline reflux gastritis. Herrington, 11:53
SYMPATHETIC NERVOUS SYSTEM
Sympathetic nervous activity in hypertension. Doyle, 11:87
SYPHILIS
Immunology of syphilis. Musher, Schell, 12:45

TESTOSTERONE
Hormones and sexual behavior in the male Davidson, 9:126
THROMBOPHLEBITIS
Role of noninvasive techniques in diagnosing leg thrombosis. Hume, Fremont-Smith, 12:57
Venous thromboembolism: diagnosis, treatment, prevention. Hirsh, 8:53
THYROGLOBULIN
Graves' ophthalmopathy: etiology and treatment. Kriss, 3:125
THYROID CRISIS
When to hospitalize the patient with thyrotoxicosis. Ingbar, 1:45
See also erratum 3:23
THYROID STIMULATOR, LONG-ACTING *see* LONG-ACTING THYROID STIMULATOR
THYROIDECTOMY
Bilateral subtotal thyroidectomy for multinodular goiter. Sedgwick, Wool, 2:70
THYROTOXICOSIS *see* HYPERTHYROIDISM
TOLBUTAMIDE
Diabetes: shifting concepts in diagnosis, therapy, etiology. 8:23
TOMOGRAPHY, RADIOGRAPHIC
Computed tomography: a major diagnostic advance. New, 2:55
TONSILLECTOMY
Teaching hospitals found heavy antibiotic users for T & A's. 3:89
TRANSFER FACTOR
Chronic aggressive hepatitis responds to transfer factor. 10:25
TREPONEMAL INFECTIONS
Immunology of syphilis. Musher, Schell, 12:45
TUMOR VIRUSES *see* ONCOGENIC VIRUSES
TUMORS *see* NEOPLASMS

ULTRASONICS
Role of noninvasive techniques in diagnosing leg thrombosis. Hume, Fremont-Smith, 12:57
Ultrasound highly recommended in diagnosis of breast cancer. 11:26B
UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
Military medicine in peacetime: the civilian physician's role. Eiseman, 6:115

VACCINES
Meningococcus vaccine – yes; gonococcus – no. 1:37
VAGINAL NEOPLASMS
Effects of maternal DES ingestion on the female genital tract. Herbst, Scully, Robboy, 10:51
VENOMS
Anaphylactic reactions to insect stings: a new approach. Lichtenstein, 3:67
VENOUS THROMBOSIS *see* THROMBOPHLEBITIS

WEISS J
Intragastric camera: through 16 simultaneous exposures it maps 95% of the stomach's interior. 3:80

X-RAY CASEBOOK (Seaman)
Case of the cloudy lungs. 7:122
Case of the dusty lung. 4:94
Case of the fatty tumor. 9:144
Case of the intramural pseudodiverticula. 6:72

YOGA
India II: a tale of untreated patients and unemployed MDs. 9:22